

1.825.99

**Case Docket No.**

jc584 U.S. PTO  
09/432351  
11/02/99

For: **A SINGLE USE LANCET ASSEMBLY**

  X     1   sheet(s) of drawings.

\_\_\_\_\_ An assignment of the invention to:

\_\_\_\_ Certified copy(ies) of the following application(s), the priority of which is hereby claimed under 35 USC §119:

  X   A verified statement to establish small entity status under 37 C.F.R. 1.9 and 37 CFR 1.27.

The filing fee has been calculated as shown below:

			<u>Small Entity</u>		<u>Other Than A Small Entity</u>	
	<u>No. Filed</u>		<u>No. Extra</u>	<u>Rate</u> <u>Fee</u>	<u>Rate</u> <u>Fee</u>	
Basic Fee				\$380		\$760
Total Claims	25	- 20 = 5	x 9 =	45	x 18 =	
Independent claims	2	- 3 = 0	x 39 =		x 78 =	
Multiple claims presented			x 130 =		x 260 =	
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11-2-99  
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NC59/1.825.9

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Steven Schraga

Serial No.:

Filing Date: November 2, 1999

For: A SINGLE USE LANCET ASSEMBLY

2800 S.W. Third Avenue  
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November 2, 1999

Honorable Commissioner of Patents and Trademarks

Washington, D.C. 20231

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Respectfully submitted,

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## INDEPENDENT INVENTOR - SMALL ENTITY STATUS

Applicant or Patentee: Steven Schraga Attorney's  
Serial or Patent No.: \_\_\_\_\_ Docket No.: 1.825.99  
Filed or Issued: \_\_\_\_\_  
For: A SINGLE USE LANCET ASSEMBLY

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY  
STATUS (37 CFR 1.9(f) and 1.27(b) - INDEPENDENT INVENTOR

As a below named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 CFR 1.9(c) for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, to the Patent and Trademark Office with regard to the invention entitled,

A SINGLE USE LANCET ASSEMBLY  
described in

☒ the specification filed herewith.  
☐ application serial no. \_\_\_\_\_, filed \_\_\_\_\_  
☐ patent no. \_\_\_\_\_, issued \_\_\_\_\_

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FULL NAME \_\_\_\_\_  
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I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF INVENTOR STEVEN SCHRAGA NAME OF INVENTOR NAME OF INVENTOR

Signature of Inventor

Date November 1, 1999 Date Date

## A SINGLE USE LANCET ASSEMBLY

BACKGROUND OF THE INVENTIONField of the Invention

The present invention relates to a single use lancet assembly which is substantially compact, yet effective for piercing a patient's finger or other body part to obtain a blood sample. The single use lancet device is further configured to be substantially safe to transport and to ensure that subsequent uses of a contaminated lancet tip cannot occur.

Description of the Related Art

Lancets are commonly utilized instruments which are employed both in hospitals and other medical facilities, as well as by private individuals, such as diabetics, in order to prick or pierce a patient's skin, typically on a finger of a patient, thereby leading to the generation of a blood sample which can be collected for testing. Because of the wide spread use of such lancets, there are a variety of lancet devices which are available for utilization by patients and/or practitioners in a variety of different circumstances.

For example, a typical lancet may merely include a housing with a sharp piercing tip that is pushed into the patient's skin. More commonly, however, lancet devices, which house a

1 piercing tip and/or a lancet, have been developed which  
2 effectively encase and fire the lancet into the patient's skin,  
3 thereby eliminating the need for the person taking the sample to  
4 actually push the lancet tip into the skin.

5 Within the various types of specialized lancet devices, one  
6 variety are typically configured for multiple and/or repeated  
7 uses, while another category is particularly configured for  
8 single use, after which the entire device is disposed of.  
Looking in particular to the single use, disposable lancet  
devices, such devices typically include a housing which contains  
and directs or drives a piercing tip into the patient's skin,  
and which is disposed of along with the used lancet. Naturally,  
so to make such disposable devices cost effective for frequent  
use, such devices tend to be rather simplistic in nature  
providing only a sufficient mechanism for firing, and not overly  
complicating the design so as to minimize that cost.

19 While existing single use devices are generally effective  
20 for achieving the piercing of the skin required for effective  
21 operation, such single use, disposable devices typically do not  
22 incorporate a large number of safety features to ensure the safe  
23 use and disposal of the device. For example, one primary area  
24 of safety which must be addressed with all lancet devices  
25 pertains to the purposeful and/or inadvertent reuse of a  
contaminated lancet. Unfortunately, most currently available  
single use lancet devices are configured such that after a use

1 thereof has been achieved, it is possible for a patient to re-  
2 cock the device, thereby allowing for a subsequent,  
3 inappropriate use.

4 As a result, it would be highly beneficial to provide a  
5 single use lancet device which is substantially compact and  
6 disposable, can be manufactured in a substantially cost  
7 effective manner, and which nevertheless is substantially safe  
8 to utilize, affirmatively preventing re-use, once contaminated.

#### SUMMARY OF THE INVENTION

The present invention relates to a single use lancet device configured to pierce a patient's skin and be useable only a single time, thereby preventing reuse of a contaminated lancet piercing tip. In particular, the present single use lancet device includes a housing having an open interior area and an access opening defined therein. The housing is preferably compact and includes a lancet disposed within its open interior.

19 Looking to the lancet, it is preferably of the type which  
20 includes a body and a piercing tip. It is the piercing tip which  
21 includes the pointed configuration structured to penetrate or  
22 pierce a patient's skin for the drawing of blood. Moreover, the  
23 lancet is cooperatively disposed within the open interior of the  
24 housing such that the lancet may move between at least a cocked  
25 orientation and a piercing orientation wherein the patient's skin is penetrated by the piercing tip.

1        Also operatively associated with the lancet is a driving  
2 assembly. The driving assembly is structured to move or drive  
3 the lancet, at least temporarily, into the piercing orientation  
4 from the cocked orientation. Preferably, however, the device is  
5 configured such that the cocked orientation is generally  
6 maintained until affirmatively released by a user. Along these  
7 lines, the present single use lancet device also includes an  
8 actuation button operatively associated with the lancet. The  
actuation button is structured to protrude from the housing, at  
least when the lancet is disposed in the cocked orientation, so  
as to be effectively actuatable. When the lancet is in the  
cocked orientation, the actuation assembly maintains the lancet  
in that cocked orientation, however, when it is actuated, such  
as by being pushed inward, the lancet is released from the  
cocked orientation and the driving assembly propels the lancet  
at least temporarily into its piercing orientation wherein the  
piercing tip protrudes through the access opening of the  
housing.

19        In order to ensure that lancet device can only be used a  
20 single time, the present single use lancet device further  
21 includes abutment structure cooperatively disposed between the  
22 housing and the lancet. The abutment structure is configured to  
23 prevent the lancet from moving into the cocked orientation after  
24 movement into the piercing orientation. Preferably, the  
25 abutment structure includes a shoulder element and a restrictor

1 panel operatively associated with the lancet and the housing.  
2 In particular, the shoulder element is structured to pass over  
3 the restrictor panel when the lancet moves from its cocked  
4 orientation to its piercing orientation. Conversely, however,  
5 when a user attempts to move the lancet back into the cocked  
6 orientation after it moved into the piercing orientation, the  
7 restrictor panel abuts the shoulder element preventing further  
8 movement. As a result, movement of the lancet into the cocked  
9 orientation is prevented once the lancet has been used a single  
time, and subsequent uses of a contaminated lancet are  
prevented.

#### BRIEF DESCRIPTION OF THE DRAWINGS

For a fuller understanding of the nature of the present invention, reference should be had to the following detailed description taken in connection with the accompanying drawings in which:

Figure 1 is a perspective illustration of an embodiment of the single use lancet device of the present invention;

Figure 2 is a side cross section view of the single use lancet device of the present invention in an unused, initially un-cocked orientation;

Figure 3 is a side cross section view of the single use lancet device of the present invention in a cocked orientation;

Figure 4 is a side cross section view of the single use



1 lancet device of the present invention after it has moved into  
2 a piercing orientation from the cocked orientation;

3 Figure 5 is a front cross section view of the single use  
4 lancet device of the present invention; and

5 Figure 6 is a side cross section view of another embodiment  
6 of the single use lancet device of the present invention after  
7 the lancet has moved from the cocked orientation through the  
8 piercing orientation.

9 Like reference numerals refer to like parts throughout the  
several views of the drawings.

#### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Shown throughout the Figures, the present invention is directed towards a single use lancet device, generally indicated as 10. In particular, the single use lancet device 10 of the present invention includes a housing, generally indicated as 20. The housing 20 is preferably substantially small and compact, and may be made of one or a plurality of segments, preferably of a generally rigid, disposable material, such as plastic. The housing 20 includes an at least partially opened interior 28 and at least one access opening 22 defined therein. The open interior 28 of the housing 20 is preferably sized and configured to effectively receive a lancet, generally 30 therein.

24 In particular, the lancet device 10 of the present  
25 invention also comprises a lancet 30. The lancet 30 preferably

1 includes a body 32 and a piercing tip 34. The piercing tip 34  
2 is what will be used to pierce a person's skin so as to draw  
3 blood to be utilized for a sample and or test procedure.  
4 Moreover, the body 32 may be the shaft of the piercing tip 34  
5 and/or an additional structure such as that depicted in the  
6 figures. Regardless, however, the lancet 30 is structured to  
7 move within the open interior 28 of a housing 20, preferably at  
8 least between a cocked orientation, as depicted in Figure 3, and  
9 a piercing orientation wherein the piercing tip 34 of lancet 30  
at least temporarily protrudes through the access opening 22.

Looking in further detail to the illustrated lancet device  
10, and the path of movement of the lancet 30 within the housing  
20, when the lancet device 10 is initially obtained for use, the  
lancet 30 is preferably maintained in an un-used, initially un-  
cocked and pre-fired orientation, as best seen in Figure 2. In  
this initially un-cocked and pre-fired orientation a protective  
cover 40 preferably extends into the open interior 28 of the  
housing 20 so as to at least partially and removably cover the  
piercing tip 34 of the lancet 30, thereby maintaining the safety  
and sterility of the piercing tip 34 when not being used. In  
this regard, the protective cover 40 may be formed from a  
variety of preferably rigid materials and is structured to  
protrude from the housing 20. Furthermore, the protective cover  
40 may include an enlarged head 42 configured to facilitate  
grasping thereof.

1            Preferably utilizing the protective cover 40, the  
2 protective cover 40 is structured to be pushed inwardly into the  
3 housing by a user, as depicted by the arrows on Figure 2,  
4 thereby pushing the lancet 30 further into the housing 20. Such  
5 pushing of the lancet 30 into the housing 20 results in a  
6 positioning of the lancet 30 in its cocked orientation, best  
7 illustrated in Figure 3. Once in the cocked orientation, the  
8 protective cover 40 is then structured to be removable from the  
piercing tip 34, such as by a twisting thereof, thereby leaving  
the piercing tip 34 complete exposed for use.

The single use lancet of the present invention further  
includes a driving assembly, generally 38. The driving assembly  
38 is particularly configured to move the lancet 30 at least  
temporarily into its piercing orientation wherein the piercing  
tip 34 protrudes through the access opening 22 of the housing 20  
a desired amount. In particular, if desired a depth adjustment  
structure could be positioned at the access opening to control  
the amount which the piercing tip protrudes from the housing 20.  
19 For example, a threaded washer type element could be adjustably  
20 secured to the housing 20 in generally surrounding relation to  
21 the access opening 22.

22            Looking further to the driving assembly, preferably the  
23 driving movement occurs when the lancet 30 is released from its  
24 cocked orientation. In the illustrated embodiment, the driving  
25 assembly 38 includes a biasing element operatively disposed

1 between the lancet 30 and the housing 20. Moreover, in the  
2 illustrated embodiment a spring is preferably utilized, however,  
3 it is recognized that a variety of other driving assemblies can  
4 be utilized, including a wedge assembly, a hammer type assembly  
5 and/or a resilient material plate, segment or extension, all of  
6 which may be configured to move the lancet 30 from the cocked  
7 orientation into the piercing orientation. Further, it is  
8 preferred that based upon the sizing of the housing 20 and the  
nature and size of the driving assembly 38, that after the  
lancet 30 has moved into the piercing orientation wherein the  
piercing tip 34 protrudes through the access opening 22, the  
lancet tends to be retracted back into the housing, as best  
illustrated in Figure 4. As a result, the used piercing tip 34  
is effectively concealed within the housing 20 subsequent to  
usage, protecting against inadvertent engagement between a  
person and the used piercing tip 34.

In order to retain, and subsequently effectively release  
the lancet 30 from its cocked orientation, the single use lancet  
10 of the present invention further includes an actuation  
assembly, generally, 50. Although a variety of different  
actuation assemblies may be incorporated so as to retain and  
then release the lancet 30 from its cocked orientation, which in  
the illustrated embodiment allows the driving assembly to be  
released from its compressed orientation, the actuation assembly  
50 includes an actuation button 52. In the illustrated

1 embodiment, the actuation button 52 is structured to at least  
2 temporarily protrude from the housing 20, such as through an  
3 actuation aperture 24. Furthermore, the actuation button 52 is  
4 preferably secured, either directly or indirectly to the lancet  
5 30, so as to generally restrict movement of the lancet 30 from  
6 the cocked orientation when it protrudes from the housing 20. As  
7 a result, the cocked orientation is maintained while the  
8 actuation button protrudes from the housing 20. Specifically,  
in the illustrated embodiment, the actuation button 52 extends  
from the body 32 of the lancet 30 by a biased segment, and as  
such, by abutting the housing 20 within the actuation opening  
24, movement of the lancet 30 from the cocked orientation is  
prevented. When, however, the actuation button 52 is actuated,  
such as by being pushed inwardly, into the housing, it is at  
least temporarily concealed within the housing 20, removing the  
abutting engagement and allowing the lancet 30 to freely move  
within the housing 20, at least temporarily into the piercing  
orientation. Although the preceding defines the illustrated  
actuation assembly, it is understood that a variety of  
20 alternative actuation assemblies, such as including separate  
21 elements to retain and to release the lancet may also be  
22 provided, and or including structures which are actually part of  
23 the driving assembly, may also be provided.

24 Looking in particular to Figure 5, movement of the lancet  
25 30 through the housing 20 is preferably maintained in a

1 substantially linear path by a guide assembly. In the  
2 illustrated embodiment, the guide assembly includes at least one  
3 guide ridge 33 protruding from the body 32 of the lancet 30, and  
4 at least one corresponding guide track 25 structured to movably  
5 receive the guide ridge 33 therein. The guide track 25  
6 preferably extends at least partially along a length of the open  
7 interior 28 of the housing 20 so as to maintain the guide ridge  
8 33 effectively therein during a necessary range of motion of the  
lancet 30. As depicted in Figure 5, preferably a pair of guide  
ridges 33 are disposed on opposite sides of the lancet body 32,  
with a corresponding pair of oppositely disposed guide tracks 25  
being defined in the housing. It is of course, however,  
understood that the guide tracks 25 need not necessarily be  
directly defined in the housing 20, but may be additional  
elements secured therein, and conversely the guide track(s) may  
be defined in or on the lancet body 32, with the guide ridge(s)  
extending inwardly from the housing 20.

The single use lancet 10 of the present invention further  
includes a restrictor assembly, generally 60. The restrictor  
assembly 60 is structured to substantially prevent the lancet 30  
from moving back into the cocked orientation of Figure 3 after  
it has moved, even momentarily, into the piercing orientation  
wherein a patient's skin may be pierced and the piercing tip 34  
become contaminated. In particular, the restrictor assembly 60  
is structured such that when the lancet 30 is disposed in the

1 initially un-cocked orientation, as best seen in Figure 2,  
2 movement of the lancet 30 back into the cocked orientation can  
3 effectively result despite the restrictor assembly 60. After,  
4 however, the lancet 30 has moved into its piercing orientation  
5 wherein the piercing 34 has protruded through the access opening  
6 22 of the housing 20, the restrictor assembly is configured such  
7 that the lancet 30 can no longer be pushed back into the cocked  
8 orientation. As a result, a patient, can neither accidentally  
9 nor purposefully reuse the single use lance 10 of the present  
invention after it has been fired.

10 In the illustrated embodiment, the restrictor assembly 60  
11 includes an abutment structure cooperatively disposed between  
12 the housing 20 and the lancet 30. The abutment structure is  
13 configured to physically prevent movement of the lancet back  
14 into the cocked orientation. Preferably, the abutment structure  
15 comprises a shoulder element 62 and a restrictor panel 64  
16 configured to freely pass one another when the lancet 30 moves  
17 from the cocked orientation to the piercing orientation, but  
18 also configured to abut one another upon attempted movement of  
19 the lancet 30 back into the cocked orientation after it has  
20 moved into the piercing orientation. Looking to Figure 4, the  
21 illustrated shoulder element 62 includes an at least partially  
22 sloped and preferably biased configuration, such as an elongate  
23 biased finger that at least partially retracts inward towards  
24 the body 32 of the lancet 30 so as to facilitate passage thereof  
25

1 past the restrictor panel 64. In this regard, preferably mating  
2 slopped surfaces are provided on the shoulder element 62 and the  
3 restrictor panel 64, thereby facilitating the slided passages  
4 past one another, and indeed, promoting an at least partial  
5 retraction of the shoulder element 62 to further facilitate this  
6 passage past one another, upon movement of the lancet 30 in a  
7 first direction towards the access opening 22 of the housing 20.  
8 The shoulder element 62 is also, however, structured to  
generally expand after it has passed the restrictor panel 64,  
such as back into its normal unretracted and/or un-compressed  
orientation, such that it will abut the restrictor panel 64 upon  
attempted movement of the lancet 30 in a second direction  
opposite the access opening 22 of the housing 20.

Although an opposite configuration could be just as  
effectively utilized, in the illustrated embodiment, the biased  
finger 62 of the shoulder element extends from the lancet 30,  
preferably generally toward the piercing tip 34 of the lancet  
30., while the restrictor panel 64 protrudes from the housing  
20, extending into the open interior 28 of the housing 20.  
20 Along these lines, the restrictor panel 64 includes a protruding  
21 element preferably with the aforementioned slopped configuration  
22 which downwardly slopes away from the piercing tip 34 of the  
23 lancet 30 facilitating the aforementioned slided passage past  
24 the shoulder element 62.

25 So as to provide generally secure movement restriction



1 through effective abutment, both the shoulder element 62 and the  
2 restrictor panel 64 each preferably include abutment surfaces 63  
3 and 65, respectably. The abutment surfaces 63 and 65 are  
4 structured to generally engage and abut one another, as best  
5 illustrated in Figure 4, thereby preventing movement of the  
6 lancet 30 back into the cocked orientation. In the illustrated  
7 embodiment, the abutment surfaces 63, 65 are generally flat,  
8 although it is recognized that interlocking fingers or wedges,  
9 and/or other types of engaging structures that prevent relative  
10 movement in at least one direction could also be effectively  
utilized.

Addressing further the restrictor assembly of the present  
invention, it is understood that a variety of different  
restrictor assemblies may be effectively utilized which prevent  
movement of a lancet 30 back into a cocked orientation after the  
lancet 30 has moved sufficiently forward and/or has moved into  
the piercing orientation. As such, the embodiment illustrated  
in Figures 2 through 5 is merely a single illustration of a  
19 preferred contemplated embodiment, and other alternative  
20 embodiments are also considered within the scope of the  
21 restrictor assembly of the present invention. By way of  
22 example, and looking specifically to Figure 6, the actuation  
23 button 52 itself may comprise part of the restrictor assembly.  
24 In such an embodiment, a restrictor panel 25 is defined in the  
25 housing 20, and the actuation button 52 as part of the biased

1 finger of the shoulder element, includes an abutment surface 54  
2 which engages a confronting surface of the restrictor panel 25.  
3 In such an embodiment, the initially un-cocked orientation  
4 provides for the actuation button 52 to be initially disposed  
5 rearward of the restrictor panel 25 so as to permit movement of  
6 the lancet 30 at least initially into the cocked orientation.  
7 Moreover, in this embodiment, the previous embodiment, and/or  
8 any other alternative embodiment, if desired, the protective  
9 cover 40 may be equipped with an interior shield segment or  
10 other configuration which extends into the housing and maintains  
the biased finger of the shoulder element 62, or another  
component of the restrictor assembly, in a generally compressed  
and/or retracted orientation until the protective cover 40 is  
removed. As a result, in such an embodiment, so long as the  
protective cover 40 is maintained on the piercing tip 34, the  
lancet 30 is always able to return the cocked orientation.  
Preferably, however, re-positioning of the protective cover onto  
the piercing tip in such a manner as to be able to "reset" the  
lancet 30, allowing to move once again into the cocked  
orientation will be prevented.

21 Since many modifications, variations and changes in detail  
22 can be made to the described preferred embodiment of the  
23 invention, it is intended that all matters in the foregoing  
24 description and shown in the accompanying drawings be  
25 interpreted as illustrative and not in a limiting sense. Thus,

1 the scope of the invention should be determined by the appended  
2 claims and their legal equivalents.

3 Now that the invention has been described,

1 What is claimed is:

2 1. A single use lancet device comprising:

3 a housing, said housing including an at least partially  
4 open interior and an access opening defined therein;

5 a lancet, said lancet including a body and a piercing tip;

6 said lancet disposed in said open interior of said housing  
7 and structured to move at least between a cocked orientation and  
8 a piercing orientation;

9 a driving assembly structured to move said lancet at least  
temporarily into said piercing orientation; and

10 a restrictor assembly structured to substantially prevent  
said lancet from moving into said cocked orientation after said  
lancet has moved at least temporarily into said piercing  
orientation.

11 2. A single use lancet as recited in claim 1 wherein said  
driving assembly includes a biasing element operatively disposed  
between said lancet and said housing.

12 3. A single use lancet as recited in claim 2 wherein said  
13 biasing element comprises a spring.

14 4. A single use lancet as recited in claim 1 further  
15 comprising an actuation assembly structured to release said  
16 lancet from said cocked orientation.

17 5. A single use lancet as recited in claim 4 wherein said  
18 actuation assembly comprises a button structured to at least  
19 temporarily protrude from said housing when said lancet is

1 disposed in said cocked orientation.

2 6. A single use lancet as recited in claim 5 wherein said  
3 button is secured to said lancet and is structured to abut said  
4 housing when protruding therethrough so as to retain said lancet  
5 in said cocked orientation until disengaged from said abutting  
6 engagement.

7 7. A single use lancet as recited in claim 6 wherein said  
8 button is structured to be at least temporarily concealed by  
9 said housing after said lancet has moved out of said cocked  
orientation.

10 8. A single use lancet as recited in claim 1 wherein said  
11 restrictor assembly comprises and abutment structure  
12 cooperatively disposed between said housing and said lancet and  
13 structured to prevent said lancet from moving into said cocked  
14 orientation after movement into said piercing orientation.

15 9. A single use lancet as recited in claim 8 wherein said  
16 abutment structure comprises a shoulder element and a restrictor  
17 panel, said restrictor panel and said shoulder element  
18 structured to pass one another upon said lancet moving from said  
19 cocked orientation to said piercing orientation, and to abut one  
20 another upon attempted movement of said lancet into said cocked  
21 orientation after movement into said piercing orientation.  
22

23 10. A single use lancet as recited in claim 9 wherein said  
24 shoulder element includes a sloped, at least partially biased  
25 configuration structured to at least partially retract to

1 facilitate passage of said restrictor panel and said shoulder  
2 element past one another in a first direction corresponding  
3 movement of said lancet from said cocked orientation to said  
4 piercing orientation, and to expand subsequent said passage past  
5 one another in said first direction such that said shoulder  
6 element and said restrictor panel abut one another upon movement  
7 towards one another in a second direction generally opposite  
8 said first direction.

9 11. A single use lancet as recited in claim 9 wherein said  
shoulder element comprises a biased finger extending from said  
lancet, and said restrictor panel comprises a protruding element  
protruding from said housing.

12. A single use lancet as recited in claim 11 wherein  
said protruding element includes a sloped configuration which  
downwardly slopes away from said piercing tip of said lancet so  
as to facilitate passage thereof past said biased finger upon  
said lancet moving in a first direction towards said access  
opening.

19 13. A single use lancet as recited in claim 12 wherein  
20 said biased finger comprises an actuation button structured to  
21 release said lancet from said cocked orientation.

22 14. A single use lancet as recited in claim 1 further  
23 comprising a guide assembly operatively disposed between said  
24 lancet and said housing and structured to guide a substantially  
25 linear movement of said lancet through said housing.

1           15. A single use lancet as recited in claim 14 wherein  
2 said guide assembly comprises at least one guide ridge  
3 protruding from said body of said lancet, and at least one  
4 corresponding guide track structured to movably receive said  
5 guide ridge therein and extending at least partially along a  
6 length of said open interior of said housing.

7           16. A single use lancet as recited in claim 1 further  
8 comprising a protective cover structured to at least partially  
9 and removably cover said piercing tip of said lancet at least  
prior to movement of said lancet into said cocked orientation.

17. A single use lancet as recited in claim 16 wherein  
said protective cover is structured to protrude from said access  
opening of said housing and is structured to be pushed by a user  
so as to position said lancet into said cocked orientation.

18. A single use lancet device comprising:

a housing, said housing including an at least partially  
open interior and an access opening defined therein;

a lancet, said lancet including a body and a piercing tip;

said lancet disposed in said open interior of said housing  
and structured to move at least between a cocked orientation and  
a piercing orientation;

a driving assembly structured to move said lancet at least  
temporarily into said piercing orientation;

a shoulder element and a restrictor panel operatively  
associated with said lancet and said housing, said shoulder

1 element structured to pass over said restrictor panel upon said  
2 lancet moving from said cocked orientation to said piercing  
3 orientation, and to abut said restrictor panel upon attempted  
4 movement of said lancet into said cocked orientation after  
5 movement into said piercing orientation so as to substantially  
6 prevent said lancet from moving into said cocked orientation  
7 after said lancet has moved at least temporarily into said  
8 piercing orientation; and

9 an actuation button structured to at least temporarily  
protrude from said housing when said lancet is disposed in said  
cocked orientation so as to maintain said lancet in said cocked  
orientation.

19. A single use lancet as recited in claim 18 wherein  
said shoulder element comprises said actuation button.

20. A single use lancet as recited in claim 18 wherein  
said shoulder element extends from said lancet and said  
restrictor panel is at least partially secured to said housing.

21. A single use lancet as recited in claim 18 further  
comprising a protective cover structured to at least partially  
and removably cover said piercing tip of said lancet at least  
prior to movement of said lancet into said cocked orientation.

22. A single use lancet as recited in claim 21 wherein  
said protective cover is structured to protrude from said access  
opening of said housing and is structured to be pushed by a user  
so as to position said lancet into said cocked orientation.



1           23. A single use lancet as recited in claim 18 wherein  
2 said shoulder element comprises a biased finger extending from  
3 said lancet generally towards said piercing tip of said lancet,  
4 and said restrictor panel comprises a protruding element  
5 disposed in said housing.

6           24. A single use lancet as recited in claim 23 wherein  
7 said protruding element includes a sloped configuration which  
8 downwardly slopes away from said piercing tip of said lancet so  
9 as to facilitate passage thereof past said biased finger upon  
10 said lancet moving in a first direction towards said access  
opening.

25. A single use lancet as recited in claim 18 further  
comprising at least one guide ridge protruding from said body of  
said lancet, and at least one corresponding guide track  
structured to movably receive said guide ridge therein and  
extending at least partially along a length of said open  
interior of said housing so as to guide substantially linear  
movement of said lancet within said housing.

Abstract of the Disclosure

A single use lancet device having a housing, with an open interior and an access opening defined therein, a lancet, with a body and a piercing tip, and disposed in the open interior of the housing so as to move between a cocked orientation and a piercing orientation, a driving assembly structured to move the lancet into the piercing orientation, and a restrictor assembly having a shoulder element and a restrictor panel operatively associated with the lancet and the housing and structured to pass over the restrictor panel upon the lancet moving from its cocked orientation to its piercing orientation, and to abut the restrictor panel upon attempted movement of the lancet back into its cocked orientation after movement into the piercing orientation, thereby preventing the lancet from moving back into the cocked orientation and preventing re-use of a contaminated piercing tip.

## DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION

## English Language Division

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below, next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

**A SINGLE USE LANCET ASSEMBLY**

the specification of which

(check one)

☒ is attached hereto

\_\_\_\_\_ was filed on \_\_\_\_\_ as

Application Serial No. \_\_\_\_\_

and was amended on \_\_\_\_\_  
(if applicable)

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations §1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate have a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s)      Priority  
Claimed

(Number)	(Country)	(Day/Month/Year Filed)	Yes	No

(Number)	(Country)	(Day/Month/Year Filed)	Yes	No

(Number)	(Country)	(Day/Month/Year Filed)	Yes	No

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national PCT International filing date of this application:

(Application Serial No.)

(Filing Date)

(Status)  
(patented, pending, abandoned)

(Application Serial No.)

(Filing Date)

(Status)  
(patented, pending, abandoned)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made of information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith. (list name and registration number)

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